REMARKS/ARGUMENTS

In response to the Office Action mailed July 8, 2005, Applicants amend their application and request reconsideration in view of the amendments. In this amendment Claims 20-31 are amended, no Claims have been cancelled, no Claims have been added, so that Claims 1-32 are currently pending. No new matter has been introduced.

The Double Patenting Rejection

The Examiner has rejected Claims 1-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-23 of U.S. Patent No. 6,589,985. The Examiner contends that although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

The Applicants respectfully traverse this rejection.

Claims 1-23 of U.S. Patent No. 6,589,985 are directed to the treatment of movement disorders. Applicants submit that the subject matter of the present application is patentably distinct from the treatment of movement disorders and in fact there is minimal to no overlap at all.

Movement disorders are described in column 1 of U.S. Patent No. 6,589,985 as a broad group of disorders that may result from a variety of neurological dysfunctions directly or indirectly linked to neuronal damage or abnormalities in nervous system pathways. However, the essential feature of a movement disorder is a problem with motor or musculature control, as shown in such movement disorders as essential tremor or restless leg syndrome. While a movement disorder might result from damage to the nervous system resulting in cell death, this is not a necessary part of a movement disorder. In contrast, the invention, disclosed in the present application, is the use of the compounds of the invention to prevent or treat neurodegenerative disorders. Neurodegenerative disorders by definition involve the death or damage to the cells of the nervous system. Thus the two types of disorders may co exist and a movement disorder might be a symptom of a neurodegenerative disorder but they are otherwise entirely different disease entities and differ in both etiology and diagnostic criteria and, in most cases, do not overlap in any way.

Therefore, Applicants request the withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting.

The Rejections Under 35 U.S.C. 112 Second Paragraph

The Examiner has rejected Claims 1-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner contends that parenthetical subject matter renders the claims in which they appear indefinite because it is unclear whether or not claim limitations are intended and, in addition, the Examiner contends that improper Markush language is used in Claims 20-31. Specifically, the term "and" should be used in place of "or" when reciting options within a group beginning with the phrase "selected from the group consisting of".

Claims 1, 5, 11, 22, 25, 26, 28, 29 and 31 have now been amended to remove the parenthetical subject matter in order to more clearly define what claim limitations are intended and Claims 20-31 have been amended to correct the improper Markush language.

Therefore, the Applicants request the withdrawal of the rejection of Claims 1-32 under 35 U.S.C. 112, second paragraph

The Rejection Under 35 U.S.C. 112 First Paragraph

The Examiner has rejected Claims 1-32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner states that;

"the claims are directed to the prevention of any neurodegenerative disorder and numerous pathologies as recited in Claims 20-31. The specification provides support for cell survival rates following the administration of an enantiomer of instant Formula Ib and IIb and transient cerebral ischemia in a rat model following administration of a compound of Formula Ib.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below."

The Applicants respectfully traverses this rejection.

The Examiner contends that the claims of the present application are broad and inclusive of many disorders of diverse etiology and that one of skill in the art would be forced to test extensively many compounds to discover which particular disorder responds to that particular compound. However, as the specification clearly states, both acute and chronic neurodegenerative disorders are associated with neuronal cell death or compromise. There are many clinical and diagnostic entities with various etiologies that are considered to be neurodegenerative disorders but they all result in the death or the serious compromise of the function of nerve cells. The final common pathways by which this death or severe dysfunction is produced is much less varied than the clinical diversity of neurodegenerative conditions would suggest. The two biological experimental examples described in the specification demonstrate the efficacy of the compounds of the invention in preventing several of these final common pathways from causing cell death.

In Example 1 it was demonstrated that an enantiomer of the invention was able to prevent the activation of apoptotic mechanisms following serum withdrawal in an *in vitro* neuronal cell model. The apoptotic mechanisms involved in this model are characteristic of the causes of neuronal loss in many diverse neurodegenerative disorders. Therefore this model is considered valid for a wide variety of neurodegenerative and cell death related disorders.

In Example 2 the enantiomers of the invention were shown to reduce the volumes of neuronal injury or infarction in rat brains after transient cerebral ischemia due to middle cerebral artery occlusion. Ischemia is the most general and non-specific possible stress for neurons as it produces a depravation of both oxygen and nutrients and provokes both apoptotic and necrotic cell loss mechanisms. Thus, reduction of neuronal cell death in this model would imply efficacy of the genus of compounds of the invention in a wide variety of neurodegenerative disorders and in stroke and many other related pathological states.

Applicants submit that the that the experimental results submitted demonstrate the effectiveness of the compounds encompassed in the entire genus of compounds disclosed to

suppress the final common pathways of apoptotic and ischemic cell death mechanisms characteristic of the wide variety of neurodegenerative disorders claimed.

Therefore, the Applicants request the withdrawal of the rejection of Claims 1-32 under 35 U.S.C. 112, first paragraph

The Rejection Under 35 U.S.C. Section 102(b)

The Examiner rejects claims 1-20 and 27 under 35 U.S.C. 102(b) as being anticipated by Choi et al. U.S. Patent 5,854,283. The Examiner states, "In addition to exhibiting neuroprotective properties, convulsions, epilepsy, stroke and muscle spasm, which characterize neurodegenerative disorders, are specifically highlighted as therapeutic endpoints."

The Applicants respectfully traverse this rejection and contend that the invention of the present application is not anticipated by the disclosure of U.S. Patent 5, 854, 283.

Although the term "neurodegenerative disorders" encompasses a large number of diagnostically distinct disease entities, the efficacy of the compounds of the invention in the treatment of neurodegenerative disorders is due to a fairly circumscribed property of the disclosed genus of compounds. This property is demonstrated by the two experimental examples shown in the specification and involves the ability of these compounds to suppress the apoptotic and necrotic final common pathways of cell death that are broadly characteristic of the end stages of many diverse neurodegenerative disorders. However, the compounds of the invention also happen to also be effective anticonvulsants and therefore are also effective in treating convulsions, epilepsy and muscle spasm as are many other anticonvulsant drugs that do not also have the ability to treat neurodegenerative disorders. It is true that convulsions, epilepsy, stroke and muscle spasm may be symptoms of some neurodegenerative disorders but this certainly does not mean that any anticonvulsant that can suppress convulsions or muscle spasms, etc. can suppress the cell death that underlies and characterizes neurodegenerative disorders. These properties are entirely separate and it is coincidental that the compounds of the invention are effective in preventing cell death in the two disclosed models of neurodegenerative disorders, i.e., Examples 1 and 2, and are, in addition, anticonvulsant and antiepileptic. Therefore, the Applicants believe that the disclosure of the '283 patent does not anticipate the present invention.

Therefore, the Applicants request the withdrawal of the rejection of Claims 1-20 and 27 under 35 U.S.C. 102(b).

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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